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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,940	02/02/2007	Matthew N. Songer	82271	6140

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EXAMINER	
SCHNEIDER, LYNNSY M	
ART UNIT	PAPER NUMBER
3733	

MAIL DATE	DELIVERY MODE
11/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,940	SONGER ET AL.	
	Examiner	Art Unit	
	LYNNSY SCHNEIDER	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *63-65 and 67-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *63-65 and 67-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 78 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The disclosure does not provide support for junctures between the curved surfaces and the flats, the junctures being diametrically opposed across the screw lock member and separated by a distance that is greater than the distance between the diametrically opposed flats of the screw lock member…

Claim Rejections - 35 USC § 103

3. Claims 63-65, 67-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freid et al. (Pub. No. US 2004/0019353 A1) in view of Glumer (Pat. No. US 2,376,768).

Regarding claims 63-65, and 67-70, Freid et al. discloses a device for stabilization of adjacent vertebrae of a spine, the device comprising: a bone plate 30 (figure 12); a plurality of bores 40, 100 (figure 12) in the bone plate 30 each configured to receive a bone anchor 182 (figures 22 and 23) extending therethrough; a pair of

spaced, flat portions of one or more of the bores (bore 100) that extend substantially parallel to one another and which are spaced by a predetermined fixed distance (illustrated in figure 12); an anchor lock collar member 46 (figures 2, 12, and 26) for being rotatably received in the one bore 100 (figures 2 and 12); an upper portion 50 (figure 25) of the anchor lock collar member 46 having notches (between projections 50, figure 25) spaced circumferentially thereabout for receiving a driving tool therein to rotate the anchor lock collar member in the one bore; a lower portion 206 (figure 26) of the anchor lock collar member 46 having a split-ring construction (figure 26) so that the anchor lock lower portion 206 has facing circumferential ends (illustrated in figure 26) that are spaced apart from one another (gap 214, figure 25); a dimension of the lower portion 206 being less than the predetermined fixed distance (since the collar can freely rotate); and cooperating inner and outer surfaces of the one bore 100 flat portions and the anchor lock lower portion 206 respectively (paragraph 0069). The facing circumferential ends (illustrated in figure 26) are oriented on the anchor lock collar member 46 in a position that generally avoids contact with the bore flat portions (figure 12) so as to minimize hang-ups when the anchor lock 46 is rotated between bone anchor receiving and locking configurations. The facing circumferential ends (illustrated in figure 26) of the anchor lock collar member 46 form a gap spacing 214. The anchor lock collar member 46 has a concave inner surface (figure 26) that compresses around a convex surface of the bone anchor (figure 22 and paragraph 0073, sentences 2 and 3) when the anchor lock is in the clamped, bone anchor locking configuration. The bone plate 32/34 can be made of stainless steel or titanium (paragraph 0061).

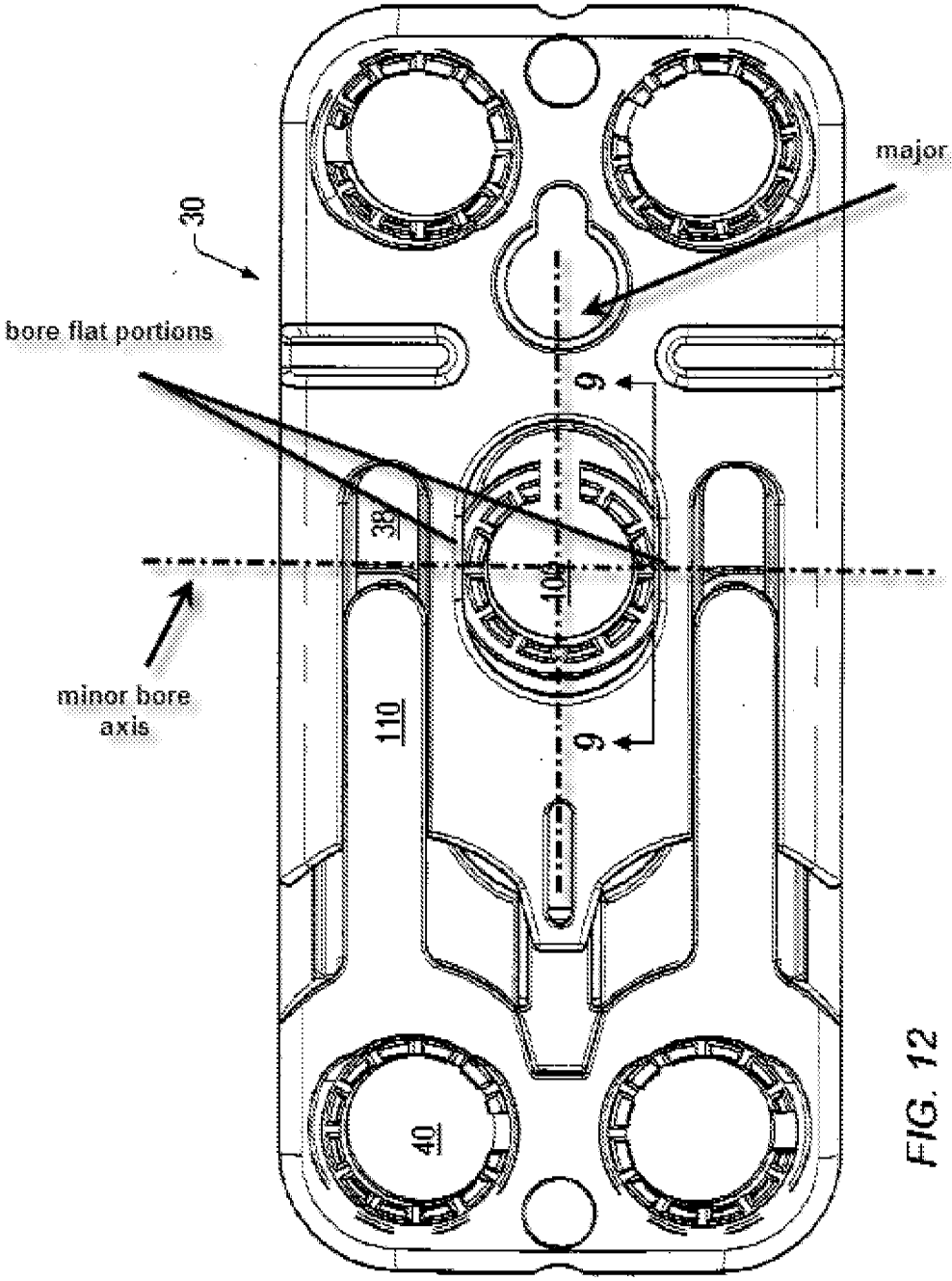

major bore axis
30
bore flat portions
9
38
104
minor bore axis
110
9
40

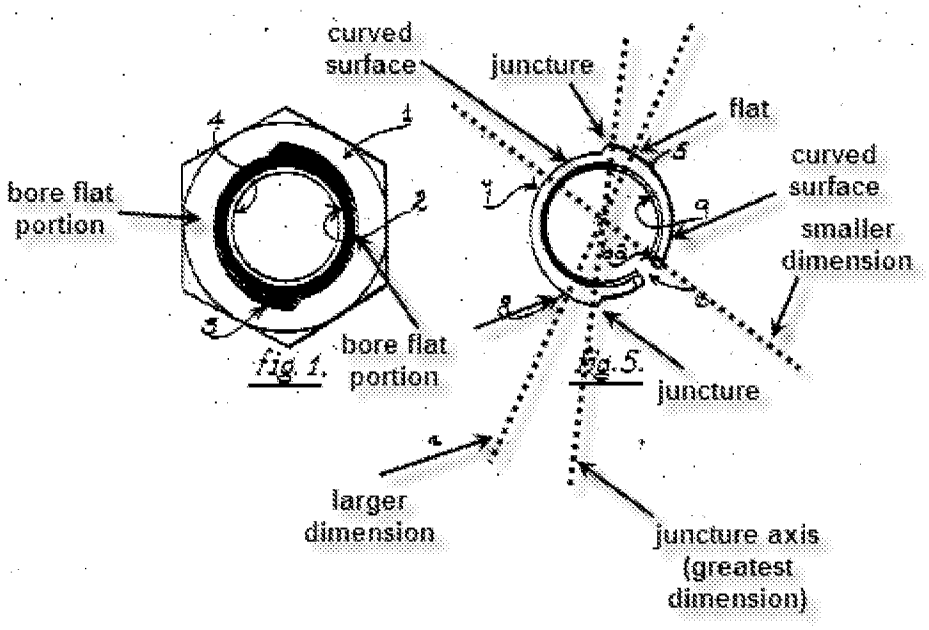
FIG. 12

Freid et al. does not disclose a larger dimension and a smaller dimension of the anchor lock lower portion having respective axes that extend through a center of the split ring anchor lock collar member substantially orthogonal to each other with the larger dimension being greater than the predetermined fixed distance and the smaller dimension being less that the predetermined fixed distance, the anchor lock lower portion including two substantially flat surfaces that are diametrically opposed to one another along the larger dimension axis, wherein the cooperation between the bore flat portions and the anchor lock lower portion causes the facing ends to shift toward each other with approximately 90 degrees of rotation of the anchor lock collar member from an open, bone anchor receiving configuration with the larger dimension axis oriented to be substantially parallel to the bore flat portions, to a clamped, bone anchor locking configuration with the larger dimension axis oriented to be substantially perpendicular to the bore flat portions, with the flat surfaces abutting the bore flat portions, so that a bone anchor extending through the one bore and the anchor lock collar member therein is locked in the one bore against back out therefrom. Freid et al. also does not disclose wherein each substantially flat surface is adjacent an anchor lock camming surface to that when the anchor lock collar member is rotated between the bone anchor receiving and locking configurations, the transition between the anchor lock camming surfaces camming against the bore flat portions and the anchor lock substantially flat surfaces abutting the bore flat portions provides tactile feedback to a surgeon that the anchor lock has been shifted to the locking configuration. Freid et al. also does not disclose that the gap spacing is positioned in a predetermined location when the anchor lock

collar member is shifted to the bone anchor locking configuration to allow a surgeon to visually recognize when the anchor lock has been rotated to the locking configuration.

Glumer teaches an anchor lock 5 (figure 5) having a larger dimension (illustrated in figure 5) and a smaller dimension (illustrated in figure 5) having respective axes that extend through a center of the split ring anchor lock collar member substantially orthogonal to each other (figure 5), the anchor lock including two substantially flat surfaces 8 (figure 5) that are diametrically opposed to one another along the larger dimension axis (figure 5), wherein the cooperation between the bore flat portions and the anchor lock causes the facing ends 6a to shift toward each other with approximately 90 degrees of rotation of the anchor lock collar member 5 from an open, bone anchor receiving configuration with the larger dimension axis oriented to be substantially parallel to the bore flat portions, to a clamped, bone anchor locking configuration with the larger dimension axis oriented to be substantially perpendicular to the bore flat portions, with the flat surfaces 8 abutting the bore flat portions, so that a bone anchor "nut" extending through the one bore and the anchor lock collar member 5 therein is locked in the one bore against back out therefrom (col. 2, lines 15-55). Each substantially flat surface 8 is adjacent an anchor lock camming surface (near ref. 7) so that when the anchor lock collar member 5 is rotated between the bone anchor receiving and locking configurations, the transition between the anchor lock camming surfaces (near ref. 7) camming against the bore flat portions and the anchor lock substantially flat surfaces 8 abutting the bore flat portions provides tactile feedback to a surgeon that the anchor lock has been shifted to the locking configuration (figure 5).

The gap spacing 6 is positioned in a predetermined location when the anchor lock collar member is shifted to the bone anchor locking configuration to allow a surgeon to visually recognize when the anchor lock 5 has been rotated to the locking configuration (as the washer is rotated, the wedge moves. The width of the wedge also decreases. Both of these features allow a surgeon to visually recognize when the washer is in the locked position). Glumer teaches that the flat/cam surfaces of the washer provide a mechanism for immobilizing a nut/bolt/washer assembly once it is in its desired orientation (col. 2, lines 44-55).



It would have been obvious to one skilled in the art at the time the invention was made to modify the anchor lock lower portion 206 of the anchor lock 46 disclosed by Freid et al. to include two substantially flat surfaces that are diametrically opposed to one another, each flat surface adjacent to an anchor lock camming surface, as taught by Glumer, thereby resulting in the anchor lock having a larger dimension (measured

from flat to flat) and a smaller dimension, the larger dimension being greater than the predetermined fixed distance of the bore, the larger dimension being located parallel to the flat portions of the recess 100 in the unlocked configuration and perpendicular to the flat portions of the recess 100 in the locked configuration, the larger dimension being shortened when in the locked configuration (after an approximately 90 degree rotation), the facing ends 212 being shifted towards each other in the locked configuration, the flats abutting the bore flat surfaces in the locked configuration, the transition between the camming surfaces and the flats providing the surgeon with tactile feedback, and the gap spacing being positioned in a prededermined location after rotation of the anchor lock collar to a locking configuration, the advantage of such a modification being that it provides a mechanism for immobilizing the bone screw, anchor lock, and plate relative to one another once they are in the desired orientation (col. 2, lines 44-55).

Regarding claims 71-73 and 78, Freid et al. discloses a device for stabilization of adjacent vertebrae of a spine, the device comprising: a bone plate 30 (figure 12); a plurality of bores 40, 100 in the bone plate configured to each receive a bone screw 182 extending therethrough; at least one of the bores being a dynamized bore 100 (figure 12) having an elongate configuration to allow a bone screw 182 extending therethrough and into a vertebrae to shift relative to the bone plate 32/34 (paragraph 0095); a pair of opposed flat portions of the dynamized bore 100 which extend along a length thereof (illustrated in figure 12); a screw lock member 46 configured to be rotatably received in the dynamized bore (figure 12) for being rotated between a screw receiving unlocked configuration and a screw locking configuration; and a substantially smooth inner

surface of the screw lock member 46 (figure 26) having an inner diameter sized in clearance with the bone screw 182 when in the screw receiving unlocked configuration (with projections 50 deflecting outward, paragraph 0073), the smooth inner surface provides a uniform clamping force about the bone screw to allow relative translation thereof in the dynamized bore and keep the bone screw from backing out therefrom (paragraph 0073). The dynamized bore 100 has both minor "second" and major "first" axes (figure 12 and paragraph 0095) The substantially smooth inner surface of the screw lock member 46 conforms to a corresponding surface on the bone screw 182 (paragraph 0073).

Freid et al. does not disclose:

-a pair of diametrically opposed outer flats of the screw lock member which face radially outward therefrom, wherein rotation of the screw lock member to the screw locking configuration brings the flats into confronting relation with the opposed bore flat portions which substantially uniformly reduces the inner diameter in size, the flats being configured to slide along the bore flat portions to permit relative translation of the bone screw and the screw lock member in the dynamized bore while keeping the bone screw from backing out therefrom,

-The rotatable screw lock member has a larger dimension and a smaller dimension, the larger dimension being brought to bear against the bore flat portions upon rotation of the screw lock member from the screw receiving configuration to the screw locking configuration which shortens the larger dimension and causes the screw lock member to constrict about the bone screw, the larger dimension of the screw lock

member being aligned with the major axis of the bore when the screw lock member is in the screw receiving configuration and the minor axis when the screw lock member is in the screw locking configuration

-the screw lock member inner surface and the corresponding surface on the bone screw having a greater coefficient of friction than a coefficient of friction between the flats of the screw lock member and the bore flat portions to permit dynamization of the rotatable screw lock member within the bore without loosening engagement of the screw lock member about the bone screw.

-the screw lock member including outer curved surfaces and junctures between the curved surfaces and the flats, the junctures being diametrically opposed across the screw lock member and separated by a distance that is greater than the distance between the diametrically opposed flats of the screw lock member such that the junctures resist rotation of the screw lock member toward the unlocked configuration.

Glumer teaches a pair of diametrically opposed outer flats 8 of the screw lock member 5 which face radially outward therefrom (figure 5), wherein rotation of the screw lock member 5 to the screw locking configuration brings the flats 8 into confronting relation with the opposed bore flat portions (illustrated in figure 1) which substantially uniformly reduces the inner diameter in size (col. 2, lines 5-55), the flats 8 being configured to slide along the bore flat portions. The rotatable screw lock member 5 has a larger dimension and a smaller dimension (illustrated in figure 5), the larger dimension being brought to bear against the bore flat portions upon rotation of the screw lock member from the screw receiving configuration to the screw locking configuration which

shortens the larger dimension and causes the screw lock member to constrict about the bone screw, the larger dimension of the screw lock member being aligned with the major axis of the bore when the screw lock member is in the screw receiving configuration and the minor axis when the screw lock member is in the screw locking configuration (col. 2, lines 5-55). The screw lock member includes outer curved surfaces (illustrated in figure 5) and junctures between the curved surfaces and the flats (figure 5), the junctures being diametrically opposed across the screw lock member and separated by a distance that is greater than the distance between the diametrically opposed flats of the screw lock member such that the junctures resist rotation of the screw lock member toward the unlocked configuration (figures 1, 4, 5; col. 2, lines 5-55). Glumer teaches that the flats of the washer provide a mechanism for immobilizing a nut/bolt/washer assembly once it is in its desired orientation (col. 2, lines 44-55)

It would have been obvious to one skilled in the art at the time the invention was made to modify the screw lock member 46 to include a pair of diametrically opposed flats which face radially outward therefrom, thereby resulting in a screw lock wherein rotation of the screw lock member to the screw locking configuration brings the flats into confronting relation with the opposed bore flat portions which substantially uniformly reduces the inner diameter in size, the flats being configured to slide along the bore flat portions to permit relative translation of the bone screw and the screw lock member in the dynamized bore while keeping the bone screw from backing out therefrom. The flats resulting in the screw lock member having a larger dimension and a smaller dimension, the larger dimension being brought to bear against the bore flat portions

upon rotation of the screw lock member from the screw receiving configuration to the screw locking configuration which shortens the larger dimension and causes the screw lock member to constrict about the bone screw, the larger dimension of the screw lock member being aligned with the major axis of the bore when the screw lock member is in the screw receiving configuration and the minor axis when the screw lock member is in the screw locking configuration, the screw lock member including outer curved surfaces and junctures between the curved surfaces and the flats, the junctures being diametrically opposed across the screw lock member and separated by a distance that is greater than the distance between the diametrically opposed flats of the screw lock member such that the junctures resist rotation of the screw lock member toward the unlocked configuration, the advantage of such a modification being that it provides a mechanism for immobilizing the bone screw, anchor lock, and plate relative to one another once they are in the desired orientation (col. 2, lines 44-55).

4. Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over Freid et al. in view of Glumer and further in view of Wagner et al. (Pat. No. US 6,454,769 B2).

Regarding claim 74, Freid et al. in view of Glumer does not disclose the screw lock member inner surface and the corresponding surface on the bone screw having a greater coefficient of friction than a coefficient of friction between the flats of the screw lock member and the bore flat portions to permit dynamization of the rotatable screw lock member within the bore without loosening engagement of the screw lock member about the bone screw (col. 10, lines 21-33; claims 25 and 26).

Wagner et al. teaches texturizing the inner surface of the screw lock 118 and the outer surface of screw head 125, thereby increasing the coefficient of friction between the screw head and the screw lock 118, for the purpose of inhibiting screw backout from the plate, while still allowing the screw lock member to move (claims 25 and 26).

It would have been obvious to one skilled in the art at the time the invention was made to modify the screw head/screw lock interacting surfaces to be texturized, thereby increasing the coefficient of friction, as taught by Wagner et al., for the purpose of preventing screw backout, while still allowing the screw lock member to move (col. 10, lines 21-33; claims 25 and 26).

5. Claims 75-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freid et al. in view of McKinlay (Pat. No. US 5,626,449).

Regarding claims 75-77, Freid et al. discloses a bone plate system for securing a plurality of bones in a desired alignment, the bone plate system comprising: a bone plate 30 (figure 12) having a top surface and a bottom surface (figure 12); a plurality of bores 40, 100 extending through the plate 30 which receive bone anchors 182 for securing the plate to the plurality of bones; a channel 102 (figure 10; paragraph 0096) of one of the bores 100, the channel being located between the top and bottom surfaces of the plate and having upper and lower surfaces extending radially outward from the bore 100 (figure 10); a locking collar 46 configured for being received in the one bore 100; a step portion (illustrated in figure 9) of the locking collar 46 having a thicker portion and a thinner portion (illustrated in figure 9); and a downwardly facing cam surface (illustrated in figure 9) extending between the thicker and thinner portions (figure 9) of the locking

collar step portion configured from camming up against the channel lower surface so that rotation of the locking collar toward a locked configuration thereof brings the locking collar cam surface into engagement with the channel lower surface, which causes a tight wedge fit of the step portion thicker portion (peak of serration) in the channel (in the valley of channel serration 106) to avoid reverse rotation back toward an unlocked configuration of the collar in the bore 100 (paragraph 0097). The cam surface of the locking collar is a ramp disposed between the thicker and thinner portions of the locking collar (figure 9). The thicker portion of the locking collar has a projection (illustrated in figure 9) that mates with the channel surface to restrict return rotation of the locking collar (figure 9; paragraph 0097)

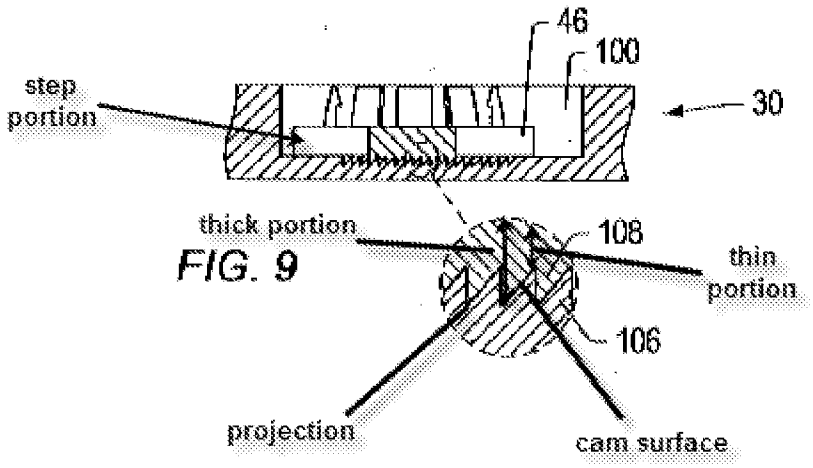


FIG. 9

Freid et al. does not disclose that the cam surface is used in a rotational manner, and that the cam surface is on the upper surface.

It would have been obvious to one skilled in the art at the time the invention was made for the cam surface to be on the upper surface and for the cam surface to engage

the channel upper surface, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

McKinlay teaches a radially disposed serrated surface 34, 36 for the purpose rotatably locking a washer assembly (figure 2). Therefore, it would have been obvious to one skilled in the art at the time the invention was made to dispose the serrations in a rotational manner since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

6. With regard the statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Freid et al. which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. Kalman v. Kimberly Clark Corp., 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Response to Arguments

7. Applicant's arguments with respect to claims63-77 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYNNSY SCHNEIDER whose telephone number is (571)270-7856. The examiner can normally be reached on Monday - Friday, 9:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. S./
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733